

CLAIMS

1. A device for performing diagnostic assays of
5 biological fluids for molecules contained therein
comprising a container dividable into at least two
chambers,

a first chamber comprising a means for absorbing
fluid in communication with antibody or antigen impregnated
10 matrix material, said impregnated matrix material being
accessible to the exterior of said first chamber through an
aperture in the roof of said first chamber;

a second chamber communicating with said first
chamber and comprising a chemical means for absorbing
15 moisture from said first chamber;

a means for pressure equilibration of said first
and second chambers;

a filter support means situated above said
antibody or antigen impregnated matrix material and in
20 communication with said impregnated matrix material through
said aperture in said roof of said first chamber,
comprising filter material affixed to said support means
for removing interfering substances present in said
biological fluids and providing chemicals to said
25 impregnated matrix material for coaction therewith to
effect the detection of said molecules.

2. A device as described in Claim 1 wherein said
means for absorbing fluid comprises a layer of porous
30 material, and a mid-layer of material, said mid-layer
material being situated between said antibody or antigen
impregnated matrix material and said porous material.

-28-

3. A device as described in Claim 2 wherein said impregnated matrix material further comprises reagents selected from the group consisting of hormones, hormone receptors, enzymes, and derivatives or combinations thereof.

4. A device as described in Claim 3 wherein said impregnated matrix material comprises antibody or antigen absorbed onto said material comprising charging a solution containing said antibody or antigen, and deflecting said charged solution in a defined pattern onto said material.

5. A device as described in Claim 3 wherein said aperture in said roof of said first chamber is funnel shaped.

6. A device as described in Claim 5 wherein said filter support means is funnel shaped.

7. A device as described in Claim 6 wherein said chemicals provided by said filter material are proteinaceous materials.

8. A device as described in Claim 7 wherein said chemicals provided by said filter material are proteinaceous materials selected from the group consisting of antibody, antibody-enzyme conjugates, and enzyme substrates.

30

-29-

9. A device as described in Claim 8 wherein said chemicals provided by said filter material for coaction for
5 said impregnated matrix material comprises associating said chemicals with said filter material by contacting said filter material with said chemicals wherein said chemicals are in powder form.

10 10. A method for impregnating immunochemicals onto matrix material useful in immunodiagnostic assays comprising dissolving said immunochemicals in solution, forming a thin stream of said solution, fragmenting said thin stream into droplets, applying a charge to said 15 droplets, passing said charged droplets through an electric field thereby deflexing said droplets in a predetermined pattern onto said matrix material.

11. A method as defined in Claim 10 wherein said 20 immunochemical reagents in said solution are selected from the group consisting of antibody, antigen, and combinations or derivatives of these molecules.

25

30

35

-30-

12. A method of assaying fluid for one or more molecules contained therein comprising:
- 5 one or more antibody molecules correspondingly reactive with said one or more molecules in said fluid;
- 10 one or more traceable second antibody molecules also correspondingly reactive with said one or more molecules in said fluid;
- 15 one or more third antibody molecules correspondingly reactive with said one or more traceable second antibodies;
- 20 wherein said one or more first antibody molecules and said one or more third antibody molecules are impregnated onto a porous matrix material in a defined orientation; and
- 25 forming a filtrate of said fluids by applying said fluids to a filtering means for removing interfering substances from said fluids and providing blocking agents to said filtrate;
- 30 coating said matrix material with said blocking agents and forming one or more complexes comprising said one or more first antibody molecules and said one or more corresponding molecules in said fluid comprising contacting said filtrate with said matrix material whereupon said one or more molecules in said fluid bind to said one or more first antibodies, and said blocking agent binds to said matrix material;
- 35 removing excess filtrate from said matrix material by contacting and retaining said excess filtrate with absorbent material;

-31-

determining the presence and/or amount of said
one or more complexes comprising contacting said matrix
5 material with one or more traceable second antibodies
having binding specificities for said corresponding one or
more molecules bound to said one or more first antibodies;
removing excess traceable second antibody;
adding a solution to said matrix material
10 containing enzyme substrate for binding to said traceable
second antibodies and revealing said complexes and removing
excess substrate solution.

13. A method as described in Claim 12 wherein said
15 one or more first antibody molecules correspondingly binds
one or more hormone antigens.

14. A method as described in Claim 13 wherein said
one or more traceable second antibody molecules bind to
20 epitopes on said hormone antigens different from epitopes
that said first antibodies are bound to.

15. A method as described in Claim 14 wherein said
first and third antibodies are of the same immunoglobulin
25 class.

16. A method as described in Claim 15 wherein said
blocking agents are proteins.

30

35

-32-

17. A method as described in Claim 16 wherein said absorbent material comprises a layer of porous material, and a mid-layer of material, said mid-layer material being situated between said matrix material and said porous material.

18. A method as described in Claim 17 wherein said one or more traceable second antibody molecules comprise one or more second antibodies bound to enzyme.

19. A method as described in Claim 18 wherein said enzyme bound to said one or more traceable second antibody molecules hydrolyzes a substrate producing a color indicative of the presence of said complex.

20. A method as described in Claim 17 wherein said one or more traceable second antibodies is bound to a different enzyme.

21. A method as described in Claim 19 wherein one or more enzymes hydrolyze different substrates producing different colors indicative of the presence of different hormone complexes formed on said matrix material.

22. A device for performing diagnostic assays of biological fluids from molecules contained therein comprising a container,

a means for absorbing fluid situated in said container and in communication with antibody or antigen impregnated matrix material, said impregnated matrix material being accessible to the exterior of said container through a funnel shaped aperture in the roof of said container;

-33-

a chemical means associated with said container
for absorbing moisture;

5 a funnel shaped filter support means situated
above said antibody or antigen impregnated matrix material,
and in communication with said matrix material through said
aperture and said roof of said container, comprising filter
material affixed to said support means for removing
interfering substances present in said biological fluids and
10 providing protein to said impregnated matrix material for
coaction therewith to effect the detection of said
molecules.

15 23. A device as described in Claim 22 wherein said
means for absorbing fluid comprises a layer of porous
material, and a mid-layer of material, said mid-layer being
situated between said antibody or antigen impregnated
matrix material and said porous material.

20 24. A device as described in Claim 23 wherein said
impregnated matrix material further comprises reagents
selected from the group consisting of hormones, hormone
receptors, enzymes, and derivatives or combinations
thereof.

25

30

35

-34-

25. A device as described in Claim 24 wherein said impregnated matrix material comprises antibody or antigen
5 absorbed onto said material comprising a solution containing said antibody or antigen, and deflecting said charged solution in a defined pattern onto said material.

10 Add
A2
15

20

25

30

35

-35-

6

TABLE 1

ICON (Hybritech, Inc.), hCG

8

Kit
requires
storage at 2-8 C

10 TEST PACK (Abbott Labs, Inc.), hCG

12

Antibody
Enzyme
Conjugate
should be stored
at 2-8 C

14

RAMP (Monoclonal Antibodes, Inc.), hCG

16

Kit
should be
kept at
2-8 C

18

-36-

TABLE 2

DIAGNOSTIC DEVICES	METHOD	SOURCE OF ANTIBODY	REACTION TIME	SENSITIVITY
Present Device	EIA, Coated Membrane	Mouse Monoclonal	2 Min.	20 mIU/ml (1st IRP)
TEST PACK hCG-URINE Abbott Laboratories	EIA, Coated Filter	Mouse Monoclonal	3 Min.	50 mIU/ml (1st IRP)
ICON® HCG-Urine Hybritech	EIA, Coated Membrane	Mouse Monoclonal	3 Min.	50 mIU/ml (1st IRP)
TANDEM Visual HCG (Urine) Hybritech	EIA, Coated Bead	Mouse Monoclonal	45 Min.	50 mIU/ml (1st IRP)
RAMP™ Urine hCG Assay Monoclonal Antibodies, Inc.	EIA, Coated Membrane	Mouse Monoclonal	3 Min.	50 mIU/ml (1st IRP)
DUOCLONE™ Slide Organon	Latex Agglutination	Mouse Monoclonal	3 Min.	500 mIU/ml (2nd I.S.)
BETA Quik Stat Pacific Biotech, Inc.	EIA, Coated Tube	Mouse Monoclonal	5 Min.	25 mIU/ml (2nd I.S.)